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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080.942	02/22/2002	Fred Zulli	1761-0013	6515

7590 09/30/2002  
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EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/080,942

Applicant(s)

ZULLI ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7 is/are rejected.
- 7) ☒ Claim(s) 4 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claim 6 is objected to because of the following informalities: In line 1, “.” should be replaced with “,”. Appropriate correction is required.
2. Claim 4 is objected to as being dependent upon a rejected base claim.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1 – 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Oils & Fats Co, LTD (Derwent 1990-234338).

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein.

Nippon Oils teaches a composition of isoflavones, specifically genistein, incorporated into liposomes (abstract).

The reference anticipates the claimed subject matter.

5. Claims 1 – 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hwang et al. (US 5948814).

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein.

Hwang teaches compositions comprising genistein incorporated into liposomes (col.7 line 39-48).

The reference anticipates the claimed subject matter.

6. Claims 1 – 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters et al. (US 6455072).

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein.

Peters teaches compositions of isoflavones incorporated into liposomes for cosmetic use (col.1 line 17-26), specifically daidzein and genistein (col.2 line 1-2).

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 – 2 and 5 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon Oils, Hwang or Peters.

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein. The isoflavones aglycone is from about 1 – 500 mg/kg of the cosmetic, or 20 – 200 mg/kg.

Nippon Oils teaches a composition of isoflavones, specifically genistein, incorporated into liposomes (abstract).

Hwang teaches compositions comprising genistein incorporated into liposomes (col.7 line 39-48).

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Peters teaches compositions of isoflavones incorporated into liposomes for cosmetic use (col.1 line 17-26), specifically daidzein and genistein (col.2 line 1-2).

The above references do not teach the claimed concentration of isoflavones in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition a composition of isoflavones and liposomes.

10. Claims 1 – 2 and 5 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saruno (JP 360061513 A) or Gorbach (US 6060070) in view of Lanzendorfer et al. (US 6180662 B1).

Saruno teaches topical cosmetic compositions comprising genistein wherein the composition exhibits antimicrobial and antioxidant activity (abstract).

Gorbach teaches cosmetic compositions of genistein and/or diadzein for treating/preventing the signs of aging (abstract). The compositions are incorporated into transdermal delivery systems and may in forms of lotions, creams, oils, sprays and gels (col.1 line 60-67).

The references do not teach the compositions incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the

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time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active ingredients of Saruno or Gorbach into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. One of ordinary skill in the art would have been further motivated to incorporate the ingredients of Gorbach into the liposome of Lanzendorfer because Gorbach specifically teaches the isoflavones compositions may be incorporated into transdermal delivery systems (of which liposomes are). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of either Saruno or Gorbach into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

11. Claims 1 – 3 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chikamatsu et al. (JP 358225004 A) and Matsuda et al. (JP 406040880 A) in view of Lanzendorfer.

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein and the composition further comprises at least one algal extract. The isoflavones aglycone is from about 1 – 500 mg p kg of the cosmetic, 20 – 200 mg p kg.

Chikamatsu teaches cosmetic compositions comprising isoflavones, specifically diadzein and genistein, for inhibiting melanin formation (or has a whitening effect) (abstract).

Matsuda teaches cosmetic compositions comprising extracts of blue-green algae that have a skin whitening effect (abstract).

The above references do not teach a composition comprising a combination of isoflavones and algae extract. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their whitening effect. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

The references do not teach the compositions wherein the active agents are incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the composition obtained by the combined references into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of Chikamatsu and Matsuda into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

The above references do not teach the claimed concentration of isoflavones in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of



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isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition a composition of isoflavones and liposomes.

12. Claims 1 – 3 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saruno and Kikuchi et al. (JP 407224278 A) in view of Lanzendorfer.

Applicant claims a cosmetic composition comprising at least one isoflavones aglycone incorporated into a liposome. Specifically, the isoflavones is genistein or daidzein and the composition further comprises at least one algal extract. The isoflavones aglycone is from about 1 – 500 mg p kg of the cosmetic, 20 – 200 mg p kg.

Saruno teaches cosmetic compositions comprising genistein wherein the composition exhibits antimicrobial and antioxidant activity (abstract).

Kikuchi teaches cosmetic compositions comprising algae extracts wherein the composition exhibits antioxidant activity (abstract).

The above references do not teach a composition comprising a combination of isoflavones and algae extract. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their antioxidant activity. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

The references do not teach the compositions wherein the active agents are incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into

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liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the composition obtained by the combined references into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of Saruno and Kikuchi into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

The above references do not teach the claimed concentration of isoflavones in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition a composition of isoflavones and liposomes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis  
September 24, 2002

A handwritten signature in black ink, appearing to be 'Ruth A. Davis', written in a cursive style.